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Oxiplex® Absorbable Gel for Spine Surgery

The leading choice of spine surgeons worldwide

Even with the best surgical technique, postoperative pain, neurological symptoms, and other long-term complications can still occur after spine surgery. Oxiplex absorbable gel acts as a temporary, protective barrier to coat and protect sensory nerves from surrounding tissues and inflammatory mediators during the body's natural healing process.

Better outcomes

In clinical studies[1,2,3] Oxiplex has demonstrated*:

- Increased likelihood of achieving high or complete reduction of leg pain.
- Significantly greater reduction of postoperative leg and back pain.
- Reduction of postoperative neurological symptoms.
- Significantly greater patient satisfaction.
- Fewer reoperations.

Safe and effective

- Demonstrated safe and effective with more than 20 years of clinical use and more than 800,000 procedures worldwide.
- Supported by numerous published clinical studies.
- Contains no pharmaceutical agents and no materials of human, animal, or bacterial origin.

Easy to use

- Sterile and ready to use – no mixing required – and conveniently stored at room temperature.
- Prepackaged, flexible applicator allows easy application.
- Clear, absorbable gel maintains operative site visibility.

Proprietary technology

- Unique, dual-polymer formula designed to offer advantages that go beyond other gel, film, and sheet technologies.

800,000+
patients treated since 2002

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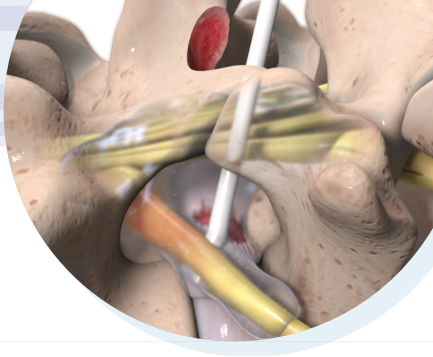
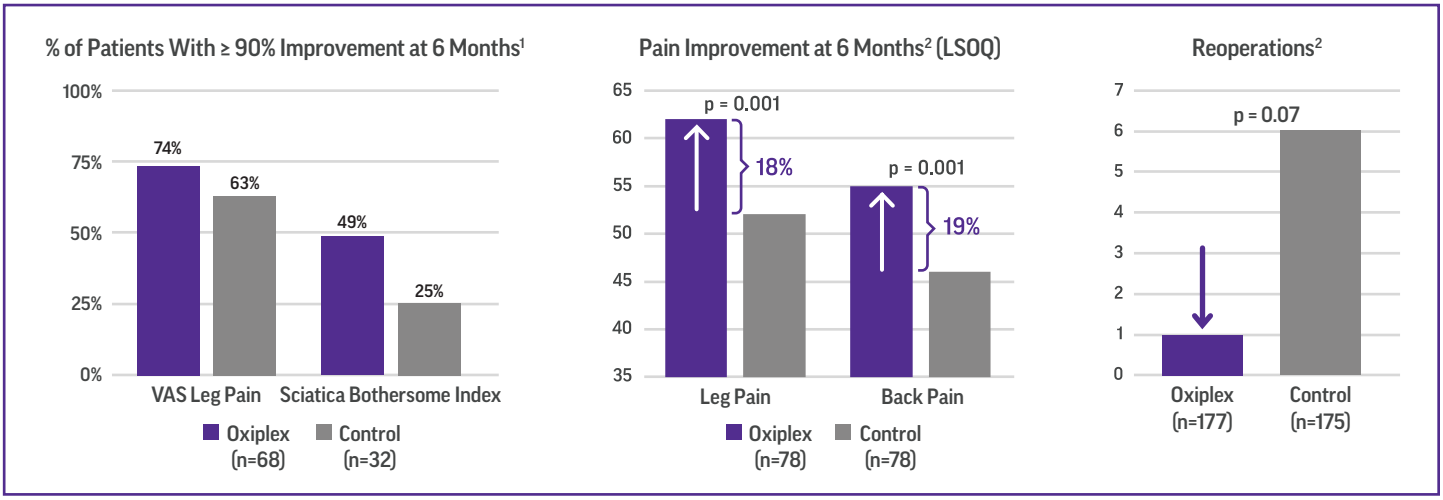


Reduced pain and neurological symptoms, fewer reoperations

Clinical studies have demonstrated the long-term benefits of using Oxiplex in lumbar spine surgery.



Unique dual-polymer technology

Our proprietary combination of two safe and extensively studied synthetic polymers – carboxymethylcellulose (CMC) and polyethylene oxide (PEO) – is designed to offer functional advantages over other technologies.

- **Tissue adherence:** The CMC in our gel allows for exceptional adherence to tissues and neural elements in a variety of anatomical environments. Oxiplex gel is designed to stay in place, throughout the body's natural healing process.[4]
- **Pain reduction:** The PEO in our gel provides a unique protective function, disrupting fibrin deposition and helping reduce the inflammatory effects of cytokines that can contribute to postoperative pain.[4]
- **Absorbable:** Oxiplex gel is naturally cleared by the body.

Product Code	Product Description
FPC-09010	Oxiplex Absorbable Gel for Spine Surgery – 3 mL
FPC-09020	Oxiplex Absorbable Gel for Spine Surgery – 1.5 mL

Oxiplex is an FDA De Novo device. It is a synthetic, absorbable gel intended as an adjunct to lumbar spinal surgery in adult patients with leg pain, back pain, and neurological symptoms undergoing discectomy to reduce leg pain and neurological symptoms. Oxiplex should only be used after hemostasis during wound closure in adult patients. It is supplied sterile, for single use only, should not be re-used or sterilized, and should not be used in the presence of infection. Healthcare professionals should refer to the Instructions for Use for a complete list of Contraindications, Warnings and Precautions.

Caution: Federal law restricts this device to sale by or on the order of a physician.

References

1. Fischgrund J, et al. Dual-Polymer Carboxymethyl Cellulose and Poly(Ethylene Oxide) Gel Reduces Leg and Back Pain in Patients With Severe Leg and Back Pain Following Single-Level Partial Discectomy. Spine 2026;51:384-392.
2. Rhyne A, et al. Oxiplex reduces leg pain, back pain and associated symptoms following lumbar discectomy. Spine 2012;37:631-641.
3. Assietti R, et al. Use of carboxymethylcellulose/polyethylene oxide gel in microdiscectomy with interlaminectomy, a case series comparison with long-term follow-up. Spine 2008;33:1762-1765.
4. DSouza A, et al. Dual-Polymer Carboxymethyl Cellulose and Poly(Ethylene Oxide)-Based Gels for the Prevention of Postsurgical Adhesions. Journal of Biomedical Materials Research Part A 2025;113:e37852.

*Compared to surgery alone at 6 months in patients with severe leg and back pain prior to surgery.

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Clinical Data

- Fischgrund J, et al. Dual-Polymer Carboxymethyl Cellulose and Poly(Ethylene Oxide) Gel Reduces Leg and Back Pain in Patients With Severe Leg and Back Pain Following Single-Level Partial Discectomy. Spine 2026;51:384-392. **View on PubMed**
- Rhyne A, et al. Oxiplex reduces leg pain, back pain and associated symptoms following lumbar discectomy. Spine 2012;37:631-641. **View on PubMed**
- Assietti R, et al. Use of carboxymethylcellulose/polyethylene oxide gel in microdiscectomy with interlaminectomy, a case series comparison with long-term follow-up. Spine 2008;33:1762-1765. **View on PubMed**
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Oxiplex®
Absorbable Gel for Spine Surgery

CLINICAL SUMMARY

Dual-Polymer Carboxymethyl Cellulose and Poly(Ethylene Oxide) Gel Reduces Leg and Back Pain in Patients with Severe Leg and Back Pain Following Single Level Partial Discectomy

Jeffrey Fischgrund, MD, David Musante, MD, Paul Arnold, MD, Kee Kim, MD, Harel Deutsch, MD, Alfred Rhyne, MD, Stephanie Cortese, David Maislin, PhD, Gere diZerega, MD

Spine 2026;51:384-392

Study Design

Prospective, randomized, double-blinded, multi-center trial.
134 patients.

Objective

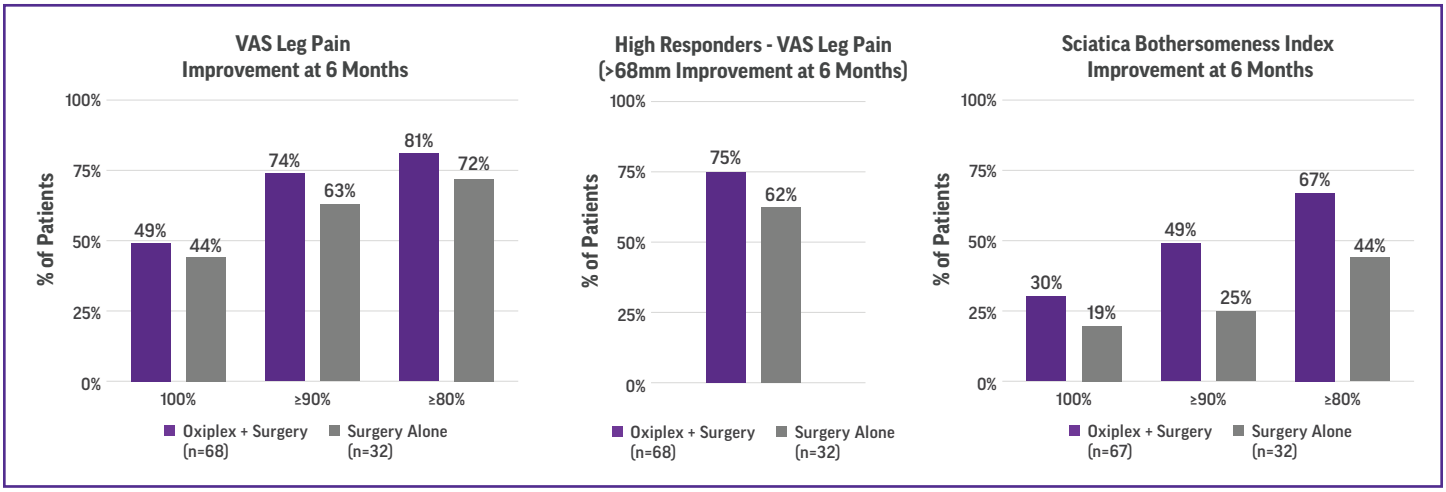
Evaluate safety and effectiveness of Oxiplex (dual-polymer gel) as an adjuvant during single-level partial discectomy in patients with severe leg and back pain.

Methods

Following single-level partial lumbar discectomy, subjects were randomized to surgery plus Oxiplex (Treatment) or surgery alone (Control). Primary endpoint was reduction in leg pain VAS at 6 months. Secondary outcomes were reductions in SBI, back pain VAS, ODI, SF-12 MCS and PCS component summaries, return to work, and patient satisfaction at 6 months.

Results

- Both Treatment and Control groups achieved significant mean improvements in ipsilateral leg pain at 6 months.
- More Treatment patients had leg pain relief at 6 months of 100%, ≥90%, and ≥80% compared to Control patients.
- 75% of Treatment patients were high responders (VAS leg pain improved by >68mm at 6 months) compared to 62% of Control patients.
- More Treatment patients achieved complete or near complete improvement in their neurological symptoms at 6 months compared to Control patients.
- No clinical differences in safety or adverse events between the Treatment and Control groups.



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OPEN

Dual-Polymer Carboxymethyl Cellulose and Poly(Ethylene Oxide) Gel Reduces Leg and Back Pain in Patients With Severe Leg and Back Pain Following Single-Level Partial Discectomy

Jeffery Fischgrund, MD,[a] David Musante, MD,[b] Paul Arnold, MD,[c] Kee Kim, MD,[d] Harel Deutsch, MD,[e] Alfred Rhyne, MD,[f] Stephanie Cortese, MSc,[g] David Maislin,[h] and Gere diZerega, MD[g]

Study Design. Prospective, randomized, double-blinded, multicenter trial.

Objective. Evaluate the safety and effectiveness of Oxiplex (dual-polymer gel) as an adjuvant during single-level partial discectomy in patients with severe leg and back pain.

Summary of Background Data. Dual-polymer gel previously reduced leg and back pain after partial lumbar discectomy in a subgroup of patients with severe leg and back pain.

Methods. Following single-level partial lumbar discectomy, participants were randomized to surgery plus dual-polymer gel (treatment) or surgery alone (control). The primary endpoint was the reduction in leg pain on the visual analog scale (VAS) at 6 months. Secondary outcomes were reductions in Sciatica Bothersomeness Index (SBI), back pain VAS, Oswestry Disability Index (ODI), SF-12 Mental (MCS) and Physical (PCS) Component Summaries, return to work, and patient satisfaction at 6-months.

Results. One hundred thirty-four participants were randomized 2:1 [ITT cohort (N = 134); n = 87 Treatment; n = 47 controls]. There were no clinical differences in safety or adverse events. Following removal of participants with protocol deviations, the Per Protocol cohort was N = 102 (n = 69 treatments; n = 33 controls). Reductions in VAS leg pain, primary outcome measure, were not different (treatment −73.9; control −72.7). However, VAS Leg Pain improved by 100% for 33 of 68 treatments (5% increase *vs.* controls); ≥90% for 50 treatments (11% increase *vs.* controls). SBI decreased by 100% for 20 of 67 Treatments (11% increase *vs.* controls); SBI decreased by ≥90% for 33 treatments (24% increase *vs.* controls). SBI leg pain component decreased ≥80% in treatments *vs.* 66% of controls; $P = 0.039$. More treatments achieved meaningful VAS back pain reduction (≥30%) than controls (93% *vs.* 88%). ODI decreased by 100% for 20 of 68 treats (13% increase *vs.* controls).

Conclusion. The addition of dual-polymer gel as an adjuvant to partial discectomy for the treatment of severe pain, reduced leg and back pain, as well as increased the proportion of participants with the best responses to surgery.

Evidence of level: Level I.

Key Words: adhesion, adjuvant, back pain, gel, leg pain, pain, polymer

(*Spine* 2026;51:384–392)

Although treatment of ipsilateral leg pain is commonly relieved by decompression of the herniated lumbar disc associated with the nerve compression, when the patient's symptoms are complicated by severe lower back pain (LBP), surgical intervention is often less successful.[1–7] The immune response following disc injury and its role in stimulating local pain following surgery is well known.[8–11] Early inflammatory signaling impacts long-term pain perception. The more stimulation pain receptors experience early on, the longer pain is perceived even after the initial inciting injury has been resolved. Pain diminishes with resolution of the tissue immune response.[12–14] Soon after discectomy, lymphocytes and macrophages infiltrate the epidural space where they release inflammatory protein mediators (inflammatory cytokines including interleukins and growth factors).[11–15] A dual-polymer gel

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J.F., A.R., and G.D. are consultants to Fziomed. S.C. is an employee of Fziomed. The remaining authors report no conflicts of interest.
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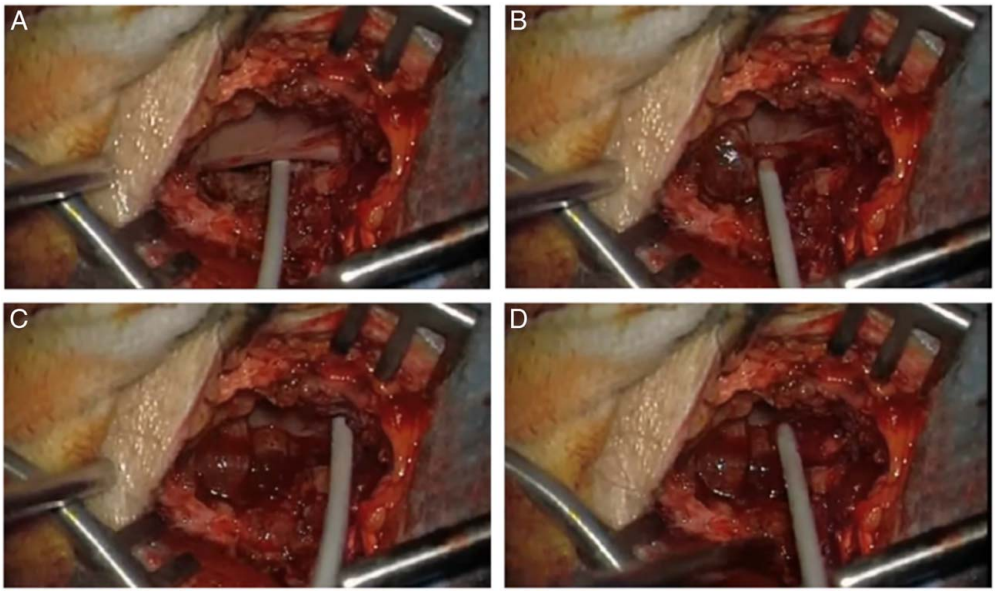

Figure 1. Use of dual-polymer gel applied in epidural space through applicator following partial discectomy: (A) placement of applicator under nerve, (B) administration of gel over posterior surface of nerve, (C) placement of applicator over top of nerve, and (D) administration of gel over anterior surface of nerve, producing circumferential coverage of nerve.

[Oxiplex: carboxymethylcellulose (CMC) and poly (ethylene oxide) (PEO); Fziomed, Inc., San Luis Obispo, CA, Fig. 1] was shown in preclinical studies[16–19] and a clinical report[20] to reduce postoperative fibrosis when applied over the surgical site following spinal surgery. The dual-polymer gel contains PEO, which partitions or disassociates proteins (inflammatory mediators), reducing their biological activity.[21–25] This should limit the availability of inflammatory mediators to pain receptors, thereby reducing their immune-driven stimulation. The feasibility of this hypothesis was recently demonstrated by chitosan hydrogels with immunoregulatory properties that remodeled the inflammatory microenvironment following spinal cord injury in a preclinical model.[26]

When used as a surgical adjuvant, dual-polymer gel was shown to reduce leg pain following partial discectomy over 6 months.[1,27–31] Further analysis identified a subgroup of patients with severe leg and LBP who had significant improvement in both following surgery when dual-polymer gel was used as an adjuvant.[1,31] These observations suggest the etiology of LBP with lumbar disc herniation may involve additional pathology in the epidural space than that of nerve compression alone.[32,33] Accordingly, a prospective, randomized, evaluator and patient blinded study was performed that only included patients with both severe leg and LBP undergoing initial surgery to decompress a herniated lumbar disc to confirm the benefit of dual-polymer gel in this difficult to treat population.

MATERIALS and METHODS

This was a prospective, randomized, multicenter, patient and evaluator-blinded study involving 17 centers in the United States to assess the safety and effectiveness of dual-polymer gel for the reduction of severe ipsilateral leg and LBP following lumbar single-level partial discectomy. The clinical protocol was approved by the FDA (NCT03433391). All participants signed informed consent and followed guidelines for experimental investigation with human subjects required by the institution with which the investigators were affiliated.

Inclusion/Exclusion Criteria

Adults (22–70 years of age) with unilateral herniation of a lumbar disc scheduled for their first surgical intervention to treat severe leg and LBP were screened. participants had severe leg pain ($\geq$60 mm) and back pain ($\geq$50 mm) scores on a visual analog 100 mm scale [VAS], radiologic evidence (MRI or CT scan) of nerve root compression, and/or an extruded or sequestered disc fragment and symptoms at the L4–L5 or L5–S1 level. Preoperative exclusion criteria were a radiographic confirmation of severe facet disease or facet degeneration at the index lumbar level, foraminal stenosis, prior spine surgery, removal of far lateral disc herniation at L4-L5 or L5-S1, trauma to the lumbar spine, or sequestered disc fragment. Intraoperative exclusions were severe facet disease or facet degeneration at the lumbar level, durotomy, spinal fusion, multilevel herniation, or involvement of more than one level, exploration of the contralateral side, or epidural fat placement at the site of the decompression. Participants underwent $\geq$6 weeks of nonoperative treatment unless pain was intractable or loss of neurological function was progressive. Participants were excluded if they received oral or epidural steroids within 4 weeks or NSAIDs within 72 hours before surgery, a lumbar puncture within 24 hours before surgery, subject to a worker's compensation claim or party to personal injury litigation.

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Site-specific randomization in blocks of 2 and 4 was determined after intraoperative eligibility was satisfied. Participants and study personnel who recorded outcome measures were blinded to treatment assignment. Controls underwent standard discectomy surgery. After surgery, participants in the treatment group had their annulus fibrosus, dura, and the exiting nerve root coated with up to 3 mL of dual-polymer gel along the anterior and posterior surfaces following completion of hemostasis. Sufficient gel was applied to fill the surgical site to the vertebral lamina. The wound was closed in routine fashion.

Sample Size Determination

Sample size was informed by a study that measured the effectiveness of dual-polymer gel in leg pain reduction in patients with severe leg and LBP undergoing lumbar surgery for a herniated disc.[31] A two-group *t* test with a 0.025 one-sided significance level was calculated at 90% power to detect a difference in means of −9.9, assuming the pooled standard deviation was 16.3, when sample sizes in the two groups were 88 and 44, respectively [a total sample size of 132 (nQuery Advisor 7.0)].

Statistical Methods

Endpoints

The primary hypothesis test was performed with a 95% two-sided confidence interval for the adjusted month 6 treatment group contrast comparing treatment to control groups using a mixed model for repeated measures.[34] Primary outcome was the change from baseline in leg pain VAS score at 6 months. Variables in the model included treatment group (surgery plus dual-polymer gel *vs.* surgery alone control), visit (week 6, month 3, and month 6), treatment group-by-visit interaction, and baseline value of VAS leg pain. An unstructured covariance matrix was used to allow variances and covariances to vary over time. The model was designed to account for correlations among responses over time. Multiple imputation was used to impute participants without month 6 values. Overlap coefficient measures (OVL) were calculated to evaluate the overlapping areas of response distributions.[35–38]

Derivation of High Responders

Receiver operating characteristics (ROC) curves were constructed to determine "responder" and "high responder" thresholds for continuous effectiveness endpoints. Participants who reported being 'Very Satisfied' on the satisfaction patient-reported outcome (PRO) provided assessments (anchors) that maximized sensitivity and specificity in identifying clinically meaningful thresholds.[39] Table 1 displays the worsened, no response, responder (clinically meaningful), and high responder thresholds for each of the continuous effectiveness endpoints using satisfaction PRO anchor-based thresholds. ROC thresholds were consistent with or higher than published thresholds.[39–42] Participants who met the responder threshold will be responders and participants who exceeded the responder threshold will be high responders.

Adverse Events

Adverse events (AEs) were assessed and categorized by the investigator. The collection of AEs began in the operating room following the incision(s) and was collected through the final visit, reported in eCRFs, and followed to resolution or study exit. A Clinical Events Committee (CEC) comprised of three clinicians (neurosurgeon, orthopedic surgeon, and interventional pain management), blind to treatment assignment, not affiliated with the Sponsor, and not participating in the study, adjudicated all SAEs and adverse events possibly related to the device or procedure.

RESULTS

Comparison of demographic, continuous, and categorical variables are shown in Tables 2 and 3. Safety analysis was conducted on the intent-to-treat (ITT) cohort, which included all participants who received study treatment (N = 134: n = 87 treatment group; n = 47 control group). The method of dual-polymer gel application, performed through microdiscectomy (71%) and non-microdiscectomy (29%) at the end of the procedures, was similar between groups. There were no adverse events considered by principal investigators or CEC to be definitely related to the device (Table 4). There were two events (hematoma resolved by drainage; foot numbness resolved by walking) considered possibly device-related. Secondary surgical interventions were similar between the treatment and control groups (6.9% *vs.* 6.4%, respectively).

Efficacy

A committee of three practicing, academic-based spinal surgeons, not affiliated with the sponsor, and blinded to treatment assignment and outcomes, adjudicated results of screening including radiologic reports and intraoperative records to identify protocol deviations. Participants without protocol deviations comprised the Per Protocol cohort used to evaluate efficacy (N = 102: n = 69 treatment; n = 33 controls).

Ipsilateral Leg Pain

There was not a significant difference in reduction of VAS leg pain between groups at 6-months (treatment: −73.9; control: −72.7). Although the primary outcome measure was not met, VAS leg pain improved by ≥ 68 points (high responders) for 51 of 68 treatment group participants (75.0%), an increase of 12.5% compared with control group participants (Fig. 2); VAS leg pain improved by 100% at 6-months (complete resolution) for 33 of 68 treatment group participants (5% increase compared with control group participants); VAS leg pain reduced by ≥ 90% for 50 of 68 treatment group participants (11% increase compared with the control group, Table 5). OVL (0.559) was consistent with good differentiation in the leg pain outcomes of both study groups (Fig. 3).

Back Pain

VAS back pain improved more in the treatment group than in the control group (−62.5 *vs.* −57.8, respectively).

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TABLE 1. Thresholds for Responder Designations Based on Responder Operating Characteristic (ROC) Analysis Using the Patient Satisfaction PRO as Anchor

Continuous effectiveness endpoint	Worsened	No response (not clinically meaningful)	Responder threshold (clinically meaningful)	High responder threshold (roc-supported optimized outcome)
VAS ipsilateral leg pain	Any increase	0 mm < decrease < 20 mm	20 mm decrease	≤−68.0 mm decrease
		0% < decrease < 30%	30% decrease	80% decrease
Sciatica Bothersomeness Index (SBI)	Any increase	0 point < decrease < 6.5 point decrease	6.5 point decrease	≤−9.0 point decrease
		0% < decrease < 30%	30% decrease	60% decrease
Oswestry Disability Index (ODI)	Any increase	0 point < decrease < 15 point	15 point decrease	≤−37.8 points
		0% < decrease < 15%	15% decrease	30% decrease
VAS back pain	Any increase	0 mm < decrease < 20 mm	20 mm decrease	≤−55.0 mm
		0% < decrease < 30%	30% decrease	80% decrease
SF-12 mental component summary (MCS)	Any decrease	0 < increase ≤ 3.77 points	> 3.77 point increase	≥ 4.59 points
SF-12 physical component summary (PCS)	Any decrease	0 < increase ≤ 3.29 points	> 3.29 point increase	≥ 16.29 points

Participants in the treatment group were more likely to achieve clinically meaningful VAS back pain reduction (defined as ≥30% reduction) at 6-months vs. the control group participants (treatment group = 93% vs.. control group = 88%).

Sciatica Bothersomeness Index (SBI)

SBI decreased by ≥90% for 33 of 67 treatment group participants (24.3% increase compared with control group participants, Table 5); SBI decreased by ≥80% for 45 of 67 treatment group participants (23.4% increase in number of high responders compared with control group participants, Fig. 2); SBI decreased by 100% for 20 of 67 treatment group participants (11% increase compared with control group participants, Table 5). SBI leg pain component decreased by 80% from baseline at 6 months in treatment group participants compared with 66% of control group participants. This 14% greater reduction in leg pain in the dual-polymer gel cohort was statistically significant ($P = 0.039$; Fig. 4). OVL (0.693) was consistent with good differentiation in SBI outcomes of study groups (Fig. 3).

Oswestry Disability Index (ODI)

ODI decreased by 100% for 20 of 68 treatment group participants (13% reduction compared with the control group participants; Table 5). Notably, all participants in both groups were considered "completely disabled" at screening (mean ODI > 50). ODIs at 6 months for the treatment and control group were 6.7 and 8.9, respectively.

TABLE 2. Demographics and Baseline Continuous Variables

	Surgery+Oxiplex		Surgery alone control		
Demographic/continuous variable	N	Mean ± SD	N	Mean ± SD	*P*
All					
Age (yr)	69	44.52 ± 13.41	33	47.09 ± 12.36	0.356
BMI (kg/m^2)	69	30.02 ± 5.48	33	29.52 ± 6.38	0.682
Height (inches)	69	68.33 ± 4.10	33	67.61 ± 3.87	0.399
Weight (lbs)	69	199.57 ± 41.97	33	191.64 ± 42.06	0.374
Female					
Age (yr)	38	43.49 ± 11.98	15	45.66 ± 13.20	0.567
BMI (kg/m^2)	38	30.03 ± 5.74	15	30.62 ± 8.23	0.769
Height (inches)	38	65.66 ± 2.57	15	64.74 ± 2.77	0.255
Weight (lbs)	38	183.75 ± 35.04	15	181.77 ± 46.65	0.867
Male					
Age (yr)	31	45.79 ± 15.09	18	48.29 ± 11.87	0.550
BMI (kg/m^2)	31	30.00 ± 5.24	18	28.59 ± 4.34	0.341
Height (inches)	31	71.60 ± 3.16	18	69.99 ± 2.93	0.085
Weight (lbs)	31	218.96 ± 42.12	18	199.86 ± 37.14	0.117
Clinical scores					
Oswestry Disability Index	69	58.13 ± 16.02	33	63.70 ± 14.26	0.092
VAS back	69	77.91 ± 16.00	33	75.55 ± 14.99	0.477
VAS ipsilateral leg	69	85.13 ± 9.76	33	83.70 ± 12.48	0.528
VAS contralateral leg	69	8.30 ± 19.32	33	7.61 ± 18.04	0.862
Sciatica Bothersomeness Index (SBI)	69	18.64 ± 4.32	33	19.45 ± 3.29	0.339
SF12 PCS	69	30.10 ± 8.26	33	26.35 ± 6.20	0.023
SF12 MCS	69	43.50 ± 11.21	33	43.95 ± 12.60	0.854

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TABLE 3. Demographic and Baseline Categorical Data

Categorical Value	N (%) Surgery+Oxiplex N = 69	Surgery alone control N = 33	*P*
Race			
American Indian or Alaska Native	0	0	> 0.999
Asian	0	0	
Black or African American	8 (12)	4 (12)	
Native Hawaiian or Other Pacific Islander	0	0	
White	59 (86)	29 (88)	
Declined to specify	0	0	
Unknown	2 (3)	0	
Ethnicity			
Hispanic or Latino	4 (6)	1 (3)	> 0.999
Not Hispanic or Latino	65 (94)	32 (97)	
Ipsilateral leg			
Right	32 (46)	14 (42)	0.832
Left	37 (54)	19 (58)	
Duration of ipsilateral leg pain			
Fewer than 6 mo	28 (41)	19 (58)	0.292
6 mo to 1 yr	21 (30)	8 (24)	
More than 1 yr	20 (29)	6 (18)	
Not applicable	0	0	
Nicotine use			
Current	12 (17)	6 (18)	0.896
Former	8 (12)	5 (15)	
None	49 (71)	22 (67)	

SF-12 Mental Component Summary (MCS) and Physical Component Summary (PCS)

The treatment group had a 5% increase in participants who had an improvement in their MCS of ≥ 5 compared with controls at 6-months (70.6% *vs.* 65.6%) and a 12.5% improvement in high responders (75.0% *vs.* 62.5%). There were no differences in PCS (58%).

Patient Satisfaction and Return to Work

Although satisfaction scores were the same for both groups at 6-months (88%), more control group participants did not return to work at 6-months compared with treatment group participants (16% *vs.* 7%).

DISCUSSION

Previously, we reported results of clinical trials in the US[1] and China[30,31] of patients with leg pain treated with laminectomy/laminotomy and dual-polymer gel as an adjuvant for decompression of disc herniation at L4-L5 and L5-S1. Use of dual-polymer gel significantly reduced both leg pain and LBP after lumbar discectomy in patients pre-

TABLE 4. Adverse Events (ITT Cohort)

AE type	Surgery+Oxiplex (n = 87) Events	Subjs	%	Surgery alone control (n = 47) Events	Subjs	%	*P*
All events	71	43	49.4	40	24	51.1	0.999
Cancer	1	1	1.1	0	0	0.0	0.999
Cardiac and vascular	4	4	4.6	5	4	8.5	0.450
Dermatologic	2	2	2.3	0	0	0.0	0.541
Gastrointestinal	1	1	1.1	1	1	2.1	0.999
Genitourinary	4	4	4.6	4	3	6.4	0.696
Immunologic	1	1	1.1	0	0	0.0	0.999
Infection	1	1	1.1	1	1	2.1	0.999
Musculoskeletal – lumbar	1	1	1.1	2	2	4.3	0.281
Musculoskeletal – Nonlumbar	3	3	3.4	3	3	6.4	0.423
Neurological – Lower extremity	2	2	2.3	4	3	6.4	0.343
Neurological – Upper extremity	1	1	1.1	0	0	0.0	0.999
Neurological – central nervous system	4	2	2.3	0	0	0.0	0.541
Pain – spine	25	23	26.4	12	12	25.5	0.999
Pain – extremity	7	6	6.9	3	3	6.4	0.999
Pain – other	3	3	3.4	3	3	6.4	0.423
Psychosocial	1	1	1.1	0	0	0.0	0.999
Respiratory	2	2	2.3	0	0	0.0	0.541
Trauma	2	2	2.3	0	0	0.0	0.541
Wound issue – index procedure	4	4	4.6	2	2	4.3	0.999
Other primary classification	2	2	2.3	0	0	0.0	0.541

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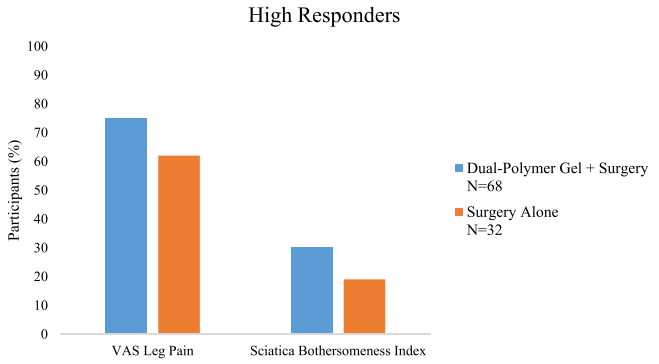

Figure 2. ROC-based threshold analysis of patient satisfaction PRO applied to endpoints at month 6 to define thresholds of high responders. Participants in the dual-polymer gel+surgery group contained a greater percentage of participants who were high responders to treatment compared with the surgery alone group.

senting with severe leg and back pain. The current study included only participants with both severe leg pain and LBP undergoing single-level lumbar laminectomy/laminotomy for partial removal of a herniated disc. Although the primary efficacy endpoint was not met using the VAS score, leg pain reduction in the treatment group was statistically greater compared with the control group using the SBI measure for leg pain (Fig. 4). In contrast to VAS,[43] the SBI leg pain score includes multiple questions as well as a statistically significant correlation ($P < 0.01$) with straight leg raise and SF-36, both long-established assessments of sciatic nerve pain from herniated lumbar discs.[44] Meaningful clinical benefit from dual-polymer gel was also shown by 5%, 11%, and 9% increases in the proportion of participants who had 100%, 90%, or 80% relief of VAS leg pain at 6 months, respectively, compared with surgery alone (Table 5). The proportion of treatment group participants who were high responders (VAS improvement of ≥ 68 mm at 6 mo) was 75% compared with 62% of controls (Fig. 2).

TABLE 5. Leg Pain, SBI, ODI Improvement At Six Months

	n (%)		
	Surgery + Oxiplex N = 68	**Surgery Alone N = 32**	**Δ**
VAS leg pain improvement			
100%	33 (49)	14 (44)	5%
Minimum 90% decrease	50 (74)	20 (63)	11%
Minimum 80% decrease	55 (81)	23 (72)	9%
Minimum 70% decrease	61 (90)	29 (91)	−1%
Minimum 60% decrease	63 (93)	32 (100)	−7%
Minimum 20% decrease	68 (100)	32 (100)	0%
Minimum 0% decrease	68 (100)	32 (100)	0%
Participants who became worse	0	0	0%
	Surgery + Oxiplex N = 67	Surgery Alone N = 32	Δ
Sciatica Bothersomeness Index (SBI) improvement at 6 Mo			
100% decrease	20 (30)	6 (19)	11%
Minimum 90% decrease	33 (49)	8 (25)	24%
Minimum 80% decrease	45 (67)	14 (44)	23%
Minimum 50% decrease	57 (85)	26 (81)	4%
Minimum 30% decrease	60 (90)	30 (94)	−4%
Minimum 10% decrease	66 (99)	32 (100)	−1%
Minimum 0% decrease	66 (99)	32 (100)	−1%
Participants who became worse	1 (1)	0	1%
	Surgery + Oxiplex N = 68	Surgery alone N = 32	Δ
Oswestry Disability Index (ODI) improvement at 6 Mo			
100% decrease	20 (29)	5 (16)	13%
Up to 100% decrease	28 (41)	12 (38)	3%
Up to 90% decrease	38 (56)	18 (56)	0%
Up to 80% decrease	57 (84)	28 (88)	−4%
Up to 50% decrease	64 (94)	31 (97)	−3%
Up to 30% decrease	68 (100)	32 (100)	0%
Up to 10% decrease	68 (100)	32 (100)	0%
Participants who became worse	0	0	0%

Evaluation of adjuvant therapies by PROs at the end of surgery is often obscured by the patient's response to surgery.[45,46] Patient's recollection of comparative pain levels asked by a single question (*e.g.*, VAS) separated from baseline by many months adds additional challenges to sample size determination of minimal clinically im-

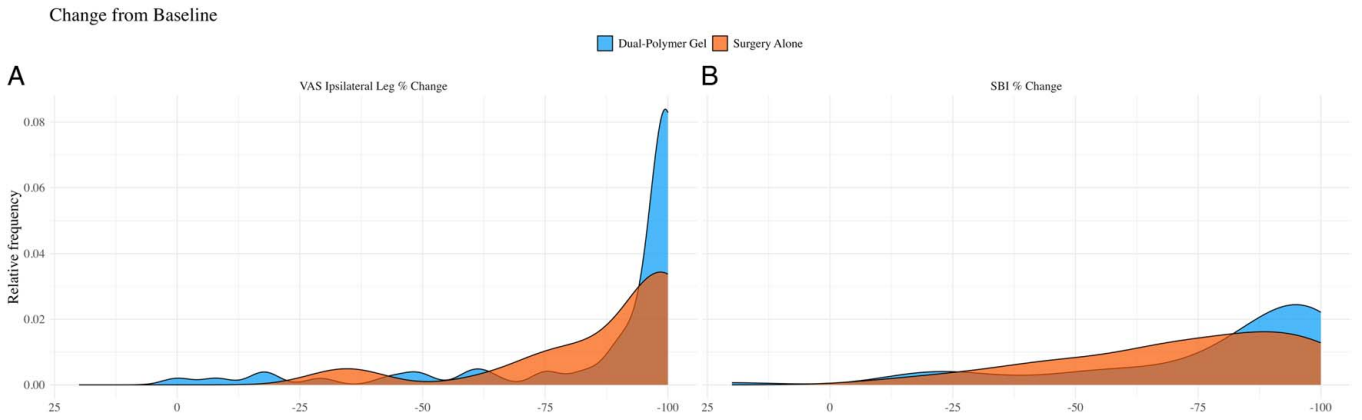

Figure 3. Distributions of participants in dual-polymer gel treatment group (gel+surgery group: blue) and surgery alone control group (orange) displayed as relative frequency of change from baseline in each participant's score. Overlap coefficients (A: 0.559; B: 0.693) demonstrated a good differentiation of responses between participants in the treatment and control groups.

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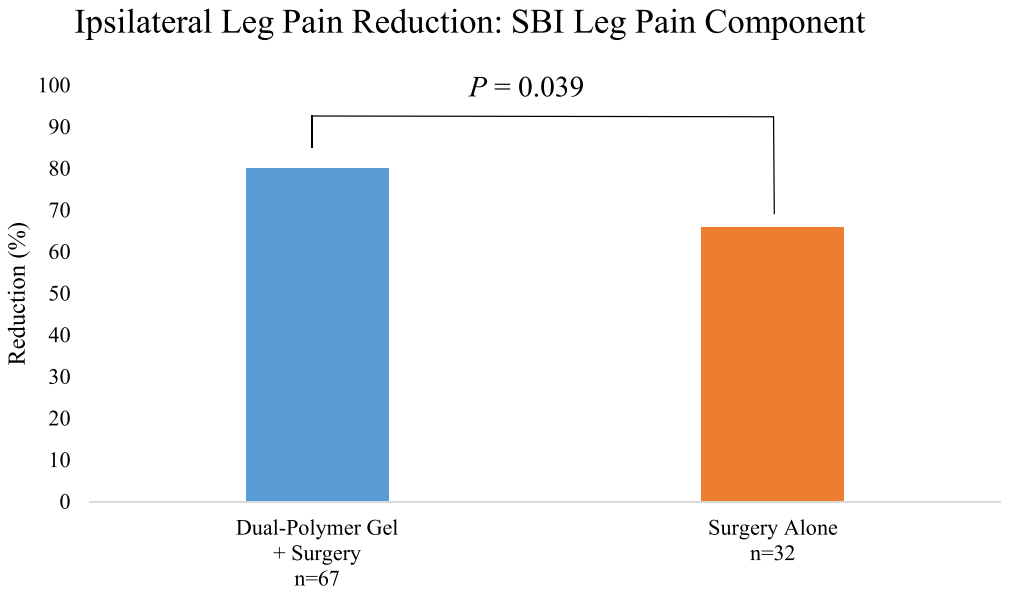

Figure 4. Sciatica Bothersomeness Index Leg Pain Component decreased by 80% from baseline at 6 months in dual-polymer gel +surgery (treatment group) compared with 66% of the surgery alone group (control group). This 14% greater reduction in leg pain in the dual-polymer gel cohort was statistically significant ($P = 0.039$).

portant differences.[47–50] In addition, site heterogeneity is common in medical device trials, especially involving surgery and PROs, further challenging the demonstration of statistical benefit from the adjuvant.[46,50,51] Responder operating characteristics (ROC) analysis, used to determine thresholds of clinical benefit, identify clinically meaningful responders and high responders to treatment.[39] Meaningful increases in clinical benefit were illustrated by comparing the distribution of their group's PRO scores. Difference in distributions is expressed as the overlap coefficient (OVL) which measures proportion of overlap in the response distributions.[35–38] There was "good differentiation" between the treatment and control group, demonstrated by a greater percentage of participants in the treatment group with larger reductions in leg pain VAS and SBI (Fig. 3).

Typical presentation of lumbar disc herniation is a patient with radicular leg pain, whereas back pain varies from none to severe. The greater the preoperative back pain relative to leg pain, usually the worse the postoperative outcome.[2,4,6,7] Patients with a herniated lumbar disc often have a greater density of sensory nerves in the annulus fibrosus and along annular tears.[52–55] Pain mediators, including the nucleus pulposus, that stimulate these sensory nerves during and after disc surgery can sensitize neural tissue to postoperative leg pain and LBP. Increase in sensory nerve excitability after decompression surgery often prolongs sensory nerve sensitization resulting in pain and hyperalgesia long after the surgical procedure.[56,57]

Epidural fibrosis can sensitize sensory nerves in the epidural space. Spinal nerve roots encased in fibrin become sensitized to external stimulation.[33,58–61] Contribution of fibrosis to chronic radicular pain following decompression surgery was demonstrated by Gerdesmeyer and colleagues who followed 381 patients for up to 10 years with chronic lumbar radicular pain. These patients experienced pain reduction after percutaneous epidural neurolysis of adhesions >4 years following surgery.[62] Fransen[20] reported a reduction in epidural fibrosis in 396 patients who presented with sciatic pain and were treated with dual-polymer gel after removal of a herniated disc. Decompressed nerve root and epidural space, including the annulus fibrosis, were covered with dual-polymer gel. Five patients underwent reoperation for recurrent herniation, two after less than a week, one after a month, and two within the first year after surgery. During the reoperation, there was little or no epidural fibrosis noted.

Results of the current study are consistent with previous dual-polymer gel trials following decompression of herniated lumbar discs in patients with severe leg pain and LBP. A multivariate analysis of participants with severe leg pain and LBP in a US study demonstrated 18.4% greater reduction in leg pain *versus* surgery alone.[1] A follow-on study in China evaluated the effectiveness of dual-polymer gel as adjunctive therapy during single-level partial lumbar discectomy.[30,31] In participants with severe leg pain and LBP, dual-polymer gel treated participants experienced a 21% greater reduction in leg pain compared with controls. An Italian series evaluated 70 consecutive participants with lumbar disc herniation undergoing microdiscectomy by the same surgeon treated with dual-polymer gel. In a subset of participants with severe leg pain and LBP, treated participants experienced a 26% greater reduction in leg pain compared with controls.[29] In these reports, there were no safety concerns or increased rate of reherniation or subsequent surgery. Potential risks

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associated with dual-polymer gel use are low due to its composition of two synthetic, biocompatible materials.[63]

CONCLUSION

The clinical data support several adjunctive benefits from the use of dual-polymer gel in spinal surgery, including a more complete reduction in leg pain and reduced neurological symptoms. The study also confirmed that participants who received dual-polymer gel had the best chance for significant or complete leg pain reduction at 6 months following surgery. Results from this study confirm and extend the safety and effectiveness of dual-polymer gel as an adjuvant in lumbar discectomy for the treatment of severe leg pain and LBP. This data aligns with the hypothesis that reducing early exposure to inflammatory mediators lowers nociceptor sensitization, leading to sustained pain reduction. Although dual-polymer gel is absorbed within 30 days, by limiting exposure to inflammatory mediators in the critical early phase following discectomy, the dual-polymer gel appears to reduce/prevent long-term sensitization of nociceptors, leading to clinically significant pain reduction at the 6-month follow-up.

➢ Key Points

- ❑ Dual-polymer gel (Oxiplex: CMC+PEO) was safe and reduced leg pain and back pain in patients presenting with both severe leg and back pain when used as an adjuvant to partial discectomy of a herniated disc at L4-L5 or L5-S1.
- ❑ Utilization of dual-polymer gel increased the likelihood of achieving high or complete resolution of leg pain at 6 months.
- ❑ Overlap coefficients provide useful illustrations of clinical outcome benefits.
- ❑ Receiver operating characteristics (ROC) used with an anchor (patient satisfaction) identify high responders to treatment.
- ❑ Use of patient-reported outcomes following surgery to measure change in clinical response over time can be challenging.

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Oxiplex®
Absorbable Gel for Spine Surgery

CLINICAL SUMMARY

Oxiplex Reduces Leg Pain, Back Pain, and Associated Symptoms After Lumbar Discectomy

Alfred L Rhyne, Scott L Blumenthal, Edmund H Frank, Ken Y Hsu, Kee D Kim, Jim A Youssef, Jeffrey C Wang, Paul Arnold, Mohammed BenDebba, Kathleen M Block, Thomas G Juarez, Richard P Chiacchierini, Ronald J Ehmsen, John S Krelle, Gere S diZerega, and the Oxiplex Clinical Study Group
Spine 2012;37:631-641

Study Design

Prospective, randomized, blinded clinical trial. 352 patients.

Objective

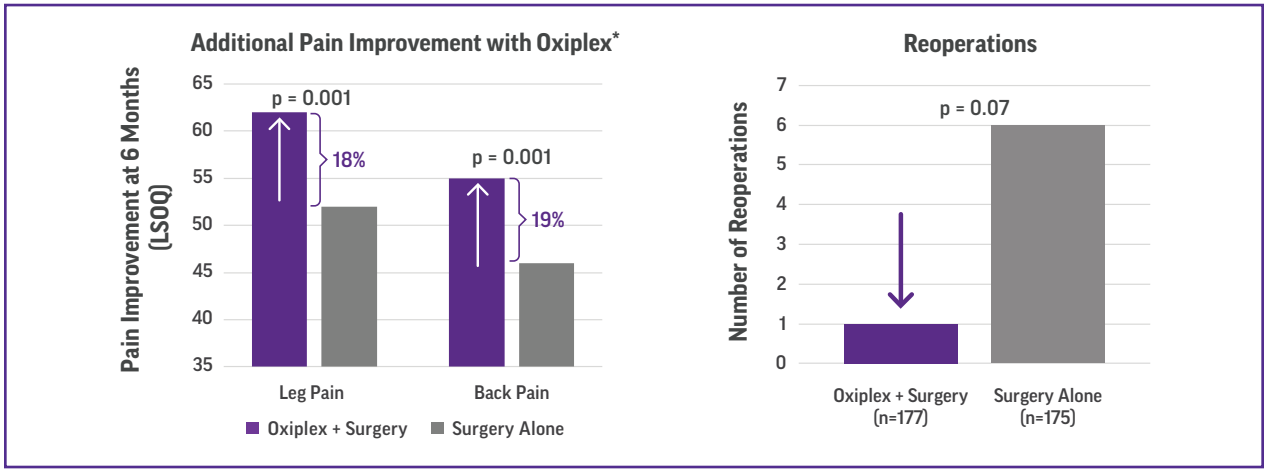
To evaluate effectiveness of Oxiplex gel for reduction of pain and associated symptoms after lumbar discectomy.

Methods

Patients undergoing single-level lumbar discectomy performed by laminectomy or laminotomy and randomized to receive either surgery + Oxiplex (treatment group) or surgery alone (control group) were assessed 6 months after surgery using quality of life questionnaire (LSOQ) and clinical evaluations.

Results

- More gel-treated patients were satisfied with outcome of their surgical treatment than control patients (P = 0.05).
- Gel-treated group showed greater reductions in pain and symptoms from baseline compared with surgery-only controls.
- Statistically significant reduction of leg pain and back pain (P < 0.01) in the treatment group compared with controls*.
- Fewer patients in the treatment group had abnormal musculoskeletal physical examinations at 6 months compared with controls.
- Patients in the treatment group had less hypoesthesia, paraesthesia, sensory loss, and fewer reoperations during the 6-month follow-up than controls.



*Compared to surgery alone at 6 months in patients with severe leg and back pain prior to surgery.

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June 17, 2025

FzioMed, Inc.
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VP, Regulatory, Quality, Clinical & Engineering
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825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: DEN240038
Trade/Device Name: Oxiplex®
Regulation Number: 21 CFR 888.3047
Regulation Name: Absorbable gel for intraoperative use in spine surgery
Regulatory Class: Class II
Product Code: QVL
Dated: July 22, 2024
Received: July 23, 2024

Dear Lisa Pritchard:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of Oxiplex®, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Oxiplex® is a synthetic, absorbable gel intended as an adjunct to lumbar spinal surgery in adult patients with leg pain, back pain, and neurological symptoms undergoing discectomy to reduce leg pain and neurological symptoms.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies Oxiplex®, and substantially equivalent devices of this generic type, into Class II under the generic name absorbable gel for intraoperative use in spine surgery.

FDA identifies this generic type of device as:

> **Absorbable gel for intraoperative use in spine surgery**. This device is an absorbable gel implant for intraoperative use in spinal procedures that is applied to nerve roots after hemostasis has been achieved and prior to closure. The device is intended as an adjunct to the surgical procedure to reduce pain and neurological symptoms.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On July 23, 2024, FDA received your De Novo requesting classification of Oxiplex®. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify Oxiplex® into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, Oxiplex® can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing Animal performance testing
Infection	Sterilization validation Shelf life testing and packaging validation Labeling
Tissue injury resulting from: • User error/improper device use • Device swelling • Byproduct formation from device breakdown	Clinical performance data Animal performance testing Non-clinical performance testing Labeling
Pain	Clinical performance data Labeling
Neurological (sensory/motor) deterioration	Clinical performance data Labeling

In combination with the general controls of the FD&C Act, the absorbable gel for intraoperative use in spine surgery is subject to the following special controls:

(1) Clinical performance data must demonstrate that the device performs as intended under anticipated conditions for use and include the following:
   (i) Evaluation of clinically relevant endpoints, such as reduction in pain or neurological symptoms, in comparison to a clinically justified comparator (e.g., the surgical procedure itself); and
   (ii) Evaluation of relevant adverse events, including impaired wound healing, pain, neurological deterioration, any unanticipated adverse device effects, and subsequent surgical interventions.

(2) Animal performance testing must evaluate the safety of the device when used as intended under anticipated conditions of use. Animal testing must include histology to assess healing and tissue response at relevant timepoints over the course of healing, as well as an evaluation of device breakdown/absorption.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use and include the following:
   (i) Characterization of the device materials;
   (ii) Characterization of gel properties, including flow properties and homogeneity;
   (iii) Evaluation of gel swelling behavior and analysis of the impact of device swelling; and
   (iv) Evaluation of byproducts from incomplete gel formation and/or device breakdown and an analysis of any adverse effects.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(7) Labeling must include the following:
   (i) A shelf life;
   (ii) Identification of material composition;
   (iii) A detailed summary of the clinical testing pertinent to use of the device, including population studied, clinical outcomes and observed adverse events;
   (iv) Information regarding any limitations of the clinical data; and
   (v) Instructions for use, including specific instructions regarding surgical site observation for achieving hemostasis prior to device use, surgical site preparation, and device placement.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the absorbable gel for intraoperative use in spine surgery they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Thomas McNamara at Thomas.McNamara@fda.hhs.gov.

Sincerely,

RDML Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

May 1, 2026

Fziomed, Inc.
% Lisa Pritchard
VP, Regulatory, Quality, Clinical & Engineering
DuVal & Associates, P.A.
825 Nicollet Mall
Medical Arts Building Suite 1820
Minneapolis, Minnesota 55402

Re: K253326
Trade/Device Name: Oxiplex
Regulation Number: 21 CFR 888.3047
Regulation Name: Absorbable Gel For Intraoperative Use In Spine Surgery
Regulatory Class: Class II
Product Code: QVL
Dated: September 30, 2025
Received: September 30, 2025

Dear Lisa Pritchard:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Oxiplex®

Absorbable Gel for Spine Surgery

CAUTION
Federal (US) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION
Oxiplex® is a synthetic, absorbable, clear, flowable, viscoelastic gel that is comprised of sodium carboxymethylcellulose (CMC) and polyethylene oxide (PEO). In spinal surgery, Oxiplex gel is applied to the surface of adjacent tissues and nerve roots at the surgical site just prior to closure to reduce pain and improve patient outcomes. Oxiplex is for single use only and is provided sterile in a pre-filled syringe together with a sterile, flexible applicator for introduction of the gel during surgery. No mixing or other preparation is required. Oxiplex is non-pyrogenic and contains no human, animal, or bacterial components. No color additives are used in the device.

INDICATIONS FOR USE
Oxiplex® is a synthetic, absorbable gel intended as an adjunct to lumbar spinal surgery in adult patients with leg pain, back pain, and neurological symptoms undergoing discectomy to reduce leg pain and neurological symptoms.

CONTRAINDICATIONS
Oxiplex is contraindicated for use in the presence of active infection. Patients known to have a history of hypersensitivity to Oxiplex or its components should not be treated with Oxiplex.

WARNINGS
WARNING: *For single patient use only.*
Reuse of Oxiplex gel or applicator may compromise sterility and affect product handling, increasing the risk of infection or device failure. **Do not reuse or re-sterilize. Discard any unused contents.**
WARNING: *Risk during pregnancy.*
The effects of Oxiplex on fetal development are unknown. Women of childbearing potential should avoid becoming pregnant until after one complete menstrual cycle following application.
WARNING: *Use in nursing women has not been evaluated.*
It is unknown whether Oxiplex is excreted in human milk. Do not administer to breastfeeding patients.
WARNING: *Do not use Oxiplex as a drug delivery system.*
Introducing medications such as antibiotics or chemotherapeutics into Oxiplex may cause unintended pharmacological effects or compromise safety.
WARNING: *Do not inject Oxiplex into blood vessels.*
Intravascular injection may result in embolism or other serious complications. Ensure the product does not enter the vascular system.
WARNING: *Hemostasis must be achieved before application.*
Applying Oxiplex in the presence of active bleeding may reduce efficacy and increase risk of complications.
WARNING: *Repair any dural leaks before applying Oxiplex.*
Unsealed dural defects may alter product behavior and pose a risk of leakage into unintended spaces.
WARNING: *Unknown safety with certain surgical materials.*
The performance of Oxiplex has not been evaluated in procedures involving:
- Hemostatic agents
- Surgical drains

PRECAUTIONS
- Risk is inherent in the use of all medical devices. To minimize the risk associated with the use of this device, it is recommended that the information for use be read by the physician and discussed with the patient prior to use of the device.
- Oxiplex is supplied sterile. DO NOT USE IF STERILE PACKAGING IS OPENED OR DAMAGED. Discard or return damaged packaging and all contents.
- Do not use after the printed expiration date on the label.
- The safety and effectiveness of Oxiplex in patients who are not skeletally mature has not been established.
- The safety and effectiveness of Oxiplex in patients with metabolic bone disease has not been established.
- Oxiplex has not been studied at the site of bone fusion.
- Foreign body reaction may occur as with any implanted surgical device.

POTENTIAL ADVERSE EVENTS
Related to general use
Adverse events associated with surgery include fever (within 36 hours postop), chills, pain, redness, swelling, itching, bleeding, bruising, hemorrhage, hematoma, seroma, wound secretions/drainage, cellulitis, weakness, stiffness, spasms, tightness at the surgical site, and death.

Related to spine surgery
Adverse events associated with spine surgery include: atelectasis/pneumonia, adjacent level disease, arachnoiditis, cavernous malformation, deep vein thrombosis, pulmonary embolism, dural tear, spinal fluid leak, fibrosis, facet fracture, wound infection, myocardial infarction, nerve injury, neurological deterioration, vascular injury, delayed union/non-union of fusion, spinal cord injury, paresis, myelopathy, including paralysis, additional surgery, failure of the surgical procedure to improve symptoms and/or function, and death.

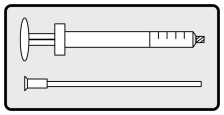
Adverse events related to lumbar spine surgery also include: cardiac disorders, visceral injury, gastrointestinal disorders, hepatobiliary disorders, cellulitis, hip fracture, incision site complication, musculoskeletal and connective tissue disorders, headache, migraine, syncope, psychiatric disorders, asthma, cholecystectomy, ileus, constipation, nausea, vomiting, chills, pyrexia, procedural pain, arthralgia, back pain, intervertebral disc protrusion, myalgia, pain in extremity, dizziness, hypoesthesia, hyporeflexia, sensory loss, insomnia, and pruritus.

Adverse events reported but not necessarily attributable to the use of Oxiplex include pain, headache, dizziness, inflammation, hematoma, wound issues, infection, neurological deterioration, and hypersensitivity reaction.

DIRECTIONS FOR USE

Oxiplex does not require refrigeration and should be stored at room temperature (2° C - 25° C / 36° F - 77° F).

This device includes:



1 – Pre-filled syringe 3mL or 1.5mL (luer lock)
1 – Applicator tip (luer lock)

Preparation

1. Remove packaging containing the pre-filled syringe and applicator from box.
2. Inspect packaging for any damage. Do not use if damaged or open. The exterior of the package is not sterile.
3. Using sterile technique, introduce syringe and applicator into sterile operating field.
4. Remove cap from luer lock end of syringe and connect the applicator to the luer lock end of the syringe; rotate until firmly attached.

Implantation

IMPORTANT: Oxiplex is to be used by physicians only. Use Oxiplex according to the instructions for use. Only up to 3 mL of Oxiplex should be used in a patient at a time.

Following the primary surgical procedure, and immediately prior to closing soft tissue incisions, use Oxiplex as follows:

1. Achieve hemostasis and repair any dural leaks.
2. Remove any hemostatic agents prior to applying Oxiplex.
3. Apply Oxiplex to the surface of adjacent tissues and nerve roots at the surgical site. Do not irrigate the site after application of Oxiplex. Surgical closure and the procedure are then concluded according to the standard technique of the surgeon.
4. Discard any opened or unused product. The used Oxiplex device may be a biohazard. Follow national, local, or institutional guidelines for disposal of biohazard material.

RESTRICTIONS

Oxiplex may only be sold, distributed, and used in accordance with the intended use. Only for professional use. The contents of this document may not be duplicated without written permission from Fziomed, Inc.

HOW SUPPLIED

Oxiplex is supplied sterile. Oxiplex is for single use only. Do not reuse. Do not re-sterilize.

MRI SAFETY INFORMATION

Oxiplex is MRI safe.

CLINICAL SUMMARY

Clinical evidence for the safety and effectiveness of Oxiplex is provided from a Confirmatory Clinical Study conducted in the United States to evaluate safety and effectiveness of Oxiplex as an adjunctive therapy during single-level discectomy at L4-L5 or L5-S1 in patients with primary leg pain of at least 60mm on a 100mm Visual Analog Scale (VAS) and back pain of at least 50mm on a 100mm VAS scale. This study was a prospective, randomized, patient-blinded, multi-center study. A 2:1 randomization was used to randomize subjects to receive either Standard of Care surgical intervention with Oxiplex or Standard of Care surgical intervention (without Oxiplex). A total of 134 subjects (87 Oxiplex, 47 control) were evaluated in Intent-to-Treat analyses that serve as the primary cohort for assessment of safety. Oxiplex subjects received an average of 2.1 mL (range 0.9 mL – 3.0 mL) of Oxiplex gel. After review by an independent Adjudication Committee, a total of 102 subjects (69 Oxiplex, 33 Control) were included in the Per Protocol cohort that served as the analysis data set for assessment of effectiveness. Follow-up visits were conducted at 6 Weeks, 3 Months, and 6 Months following the surgical procedure. The primary evaluation of effectiveness was conducted at 6 Months.

DEMOGRAPHICS

Evaluation of demographic and baseline continuous variable data for the Per Protocol cohort were balanced between the Oxiplex + Surgery and Surgery Alone control groups, except for SF-12 Physical Component Score (PCS) for which Oxiplex + Surgery had a higher mean score (p=0.023), as shown in Table 1.

Table 1: Demographics and Baseline Continuous Variable Data – Per Protocol Cohort

Demographic / Continuous Variable	Surgery + Oxiplex		Surgery Alone control		p-value[1]
	N	Mean ± SD	N	Mean ± SD	
ALL					
Age (years)	69	44.52 ± 13.41	33	47.09 ± 12.36	0.356
BMI (kg/m^2)	69	30.02 ± 5.48	33	29.52 ± 6.38	0.682
Height (inches)	69	68.33 ± 4.10	33	67.61 ± 3.87	0.399
Weight (lbs)	69	199.57 ± 41.97	33	191.64 ± 42.06	0.374
FEMALE					
Age (years)	38	43.49 ± 11.98	15	45.66 ± 13.20	0.567
BMI (kg/m^2)	38	30.03 ± 5.74	15	30.62 ± 8.23	0.769
Height (inches)	38	65.66 ± 2.57	15	64.74 ± 2.77	0.255
Weight (lbs)	38	183.75 ± 35.04	15	181.77 ± 46.65	0.867
MALE					
Age (years)	31	45.79 ± 15.09	18	48.29 ± 11.87	0.550
BMI (kg/m^2)	31	30.00 ± 5.24	18	28.59 ± 4.34	0.341
Height (inches)	31	71.60 ± 3.16	18	69.99 ± 2.93	0.085
Weight (lbs)	31	218.96 ± 42.12	18	199.86 ± 37.14	0.117
CLINICAL SCORES					
Oswestry Disability Index	69	58.13 ± 16.02	33	63.70 ± 14.26	0.092
VAS Back	69	77.91 ± 16.00	33	75.55 ± 14.99	0.477
VAS Ipsilateral Leg	69	85.13 ± 9.76	33	83.70 ± 12.48	0.528
VAS Contralateral Leg	69	8.30 ± 19.32	33	7.61 ± 18.04	0.862
Sciatica Bothersomeness Index (SBI)	69	18.64 ± 4.32	33	19.45 ± 3.29	0.339
SF12 PCS	69	30.10 ± 8.26	33	26.35 ± 6.20	0.023
SF12 MCS	69	43.50 ± 11.21	33	43.95 ± 12.60	0.854

[1]Two-sided t-test.

Evaluation of baseline categorical data for the Per Protocol cohort was balanced between the Oxiplex + Surgery and Surgery Alone control groups, as shown in Table 2.

Table 2: Demographics and Baseline Categorical Data – Per Protocol Cohort

Categorical Value	Surgery + Oxiplex N=69		Surgery Alone control N=33		p-value[1]
	N	%	N	%	
RACE					
American Indian or Alaska Native	0	0%	0	0%	>0.999
Asian	0	0%	0	0%	
Black or African American	8	12%	4	12%	
Native Hawaiian or Other Pacific Islander	0	0%	0	0%	
White	59	86%	29	88%	
Declined to specify	0	0%	0	0%	
Unknown	2	3%	0	0%	
ETHNICITY					
Hispanic or Latino	4	6%	1	3%	>0.999
Not Hispanic or Latino	65	94%	32	97%	
IPSILATERAL LEG					
Right	32	46%	14	42%	0.832
Left	37	54%	19	58%	
DURATION OF IPSILATERAL LEG PAIN					
Fewer than 6 months	28	41%	19	58%	0.292
6 months to 1 year	21	30%	8	24%	
More than 1 year	20	29%	6	18%	
Not applicable	0	0%	0	0%	
NICOTINE USE					
Current	12	17%	6	18%	0.896
Former	8	12%	5	15%	
None	49	71%	22	67%	

[1]Generalized Exact p-value.

EFFECTIVENESS SUMMARY

Evaluation of effectiveness was completed using the Per Protocol cohort, including subjects determined to meet all study inclusion/exclusion criteria aligned with the Oxiplex Indications for Use. The primary endpoint for the study was change in ipsilateral leg pain as measured by Visual Analog Scale (VAS) at the 6-month visit. The primary endpoint was not met as both Oxiplex + Surgery and Surgery Alone control groups achieved significant mean improvements in ipsilateral leg pain (-73.9 mm and -72.7 mm, respectively), but the difference between groups was not statistically significant (p=0.803).

Following the original analysis identified in the clinical study protocol, additional responder analysis was defined and conducted. A total of 5%, 11%, and 9% more Oxiplex + Surgery subjects had at least 100%, 90%, or 80% relief from ipsilateral leg pain at 6 Months, respectively, compared to Surgery Alone control subjects, as shown in Table 3.

Table 3: Ipsilateral Leg Pain High Responders at 6 Months – Per Protocol Cohort

VAS Ipsilateral Leg Pain Improvement	Surgery + Oxiplex N=68		Surgery Alone control N=32		Δ
	n	%	n	%	
100%	33	49%	14	44%	5%
Minimum 90% decrease	50	74%	20	63%	11%
Minimum 80% decrease	55	81%	23	72%	9%
Minimum 70% decrease	61	90%	29	91%	-1%
Minimum 60% decrease	63	93%	32	100%	-7%
Minimum 20% decrease	68	100%	32	100%	0%
Minimum 0% decrease	68	100%	32	100%	0%
Subjects who became worse	0	0%	0	0%	0%

VAS Ipsilateral Leg Pain was evaluated by degree of improvement, including high responder (minimum 68mm VAS improvement), moderate improvement (from 20mm to less than 68mm VAS improvement), and no improvement (less than 20mm VAS improvement). These data are shown in Table 4. An alternate presentation showing only those subjects meeting and not meeting the high responder threshold was also evaluated, as shown in Table 5, with associated pre-specified statistics following the table.

Table 4: VAS Ipsilateral Leg Pain Change by Response Threshold at 6 Months – Per Protocol Cohort

Study Group	High Responder Improvement (≤-68mm)	Moderate Improvement (-68mm < x ≤ -20mm)	No Improvement (>-20mm)	Total
Oxiplex + Surgery	51 (75.0%)	13 (19.1%)	4 (5.9%)	68
Surgery Alone	20 (62.5%)	12 (37.5%)	0 (0.0%)	32
Total	71	25	4	100

Table 5: 2x2 Table of VAS Ipsilateral Leg Pain Change by Response Threshold at 6 Months – Per Protocol Cohort

Study Group	High Responder Improvement (≤-68mm)	No Improvement (>-68mm)	Total
Oxiplex + Surgery	51 (75.0%)	17 25.0%	68
Surgery Alone	20 (62.5%)	12 37.5%	32
Total	71	29	100

Pre-specified statistics for Table 5:

- Sensitivity (SN): 0.718 [51/71] (0.614, 0.823)
- Specificity (SP): 0.414 [12/29] (0.235, 0.593)
- Positive Predictive Value (PPV): 0.750 [51/68] (0.647, 0.853)
- Negative Predictive Value (NPV): 0.414 [12/29] (0.207, 0.543)
- Risk Difference (RD): 0.125 (-0.071, 0.322)
- Odds Ratio (OR): 1.80 (0.73, 4.44)
- Chi-Squared (CS): 1.65 (p = 0.199)

More Surgery + Oxiplex subjects achieved complete or near complete improvement in their sciatica symptoms (as measured by SBI) at 6 Months, as shown in Table 6.

Table 6: Sciatica Bothersomeness Index Improvement at 6 Months – Per Protocol Cohort

Sciatica Bothersomeness Index Improvement at 6 Months	Surgery + Oxiplex N=67		Surgery Alone control N=32	
	n	%	n	%
100% decrease	20	30%	6	19%
Minimum 90% decrease	33	49%	8	25%
Minimum 80% decrease	45	67%	14	44%
Minimum 50% decrease	57	85%	26	81%
Minimum 30% decrease	60	90%	30	94%
Minimum 10% decrease	66	99%	32	100%
Minimum 0% decrease	66	99%	32	100%
Subjects who became worse	1	1%	0	0%

Effectiveness data interpretations were limited because the primary study endpoint (superiority in mean improvement of VAS Ipsilateral Leg Pain improvement over spinal surgery alone at 6 Months in the intention-to-treat data set) was not met with statistical significance. Following this, the effectiveness of Oxiplex was evaluated based on evaluation of a Per Protocol data set that was determined by an independent adjudication committee. Pain improvement data were evaluated based on observed outcomes, including post-hoc analyses with no p-values. The current clinical dataset does not specifically identify which patients will likely be high responders from using Oxiplex Gel based on their demographics and/or characteristics.

The available results indicate that the probable benefits from adjunctive use of Oxiplex during spinal surgery can include a more complete reduction in ipsilateral leg pain and reduced neurological symptoms at 6 Months.

SAFETY SUMMARY

Evaluation of safety was completed using the Intent-to-Treat cohort, including all subjects randomized in the Confirmatory Clinical Study. Safety measures evaluated included adverse events, secondary surgical interventions, and neurological status. Adverse events, secondary surgical interventions, and neurological status are summarized in Table 7, Table 8, and Table 9, respectively.

Table 7: Adverse Event Overview – Intent-to-Treat Cohort

AE Type	Surgery + Oxiplex (n=87)			Surgery Alone control (n=47)			p-value[2]
	Events	Subjs	%[1]	Events	Subjs	%[1]	
All Events	71	43	49.4%	40	24	51.1%	0.999
Cancer	1	1	1.1%	0	0	0.0%	0.999
Cardiac & Vascular	4	4	4.6%	5	4	8.5%	0.450
Dermatologic	2	2	2.3%	0	0	0.0%	0.541
Gastrointestinal	1	1	1.1%	1	1	2.1%	0.999
Genitourinary	4	4	4.6%	4	3	6.4%	0.696
Immunological	1	1	1.1%	0	0	0.0%	0.999
Infection	1	1	1.1%	1	1	2.1%	0.999
Musculoskeletal – Lumbar	1	1	1.1%	2	2	4.3%	0.281
Musculoskeletal – Non-Lumbar	3	3	3.4%	3	3	6.4%	0.423
Neurological – Lower Extremity	2	2	2.3%	4	3	6.4%	0.343
Neurological – Upper Extremity	1	1	1.1%	0	0	0.0%	0.999
Neurological – Central Nervous System	4	2	2.3%	0	0	0.0%	0.541
Pain – Spine	25	23	26.4%	12	12	25.5%	0.999
Pain – Extremity	7	6	6.9%	3	3	6.4%	0.999
Pain – Other	3	3	3.4%	3	3	6.4%	0.423
Psychosocial	1	1	1.1%	0	0	0.0%	0.999
Respiratory	2	2	2.3%	0	0	0.0%	0.541
Trauma	2	2	2.3%	0	0	0.0%	0.541
Wound Issue – Index Procedure	4	4	4.6%	2	2	4.3%	0.999
Other Primary Classification	2	2	2.3%	0	0	0.0%	0.541

[1]Percentage of subjects experiencing a specific event.

[2]Exact p-value.

Table 8: Secondary Surgical Interventions – Intent-to-Treat Cohort

Intervention Type	Surgery + Oxiplex (N=87)		Surgery Alone control (N=47)		p-value[1]
	n	%	n	%	
Reoperation	5	5.7%	2	4.3%	>0.999
Removal	0	0.0%	0	0.0%	>0.999
Supplemental Fixation	1	1.1%	2	4.3%	0.281
TOTAL	**6**	**6.9%**	**3**[**]	**6.4%**	**>0.999**
Surgery for Reherniation	4	4.6%	3	6.4%	0.670
Other Surgeries	2	2.3%	1	2.1%	>0.999

[1]Fisher's Exact Test. [**]One subject had two separate surgical interventions.

Table 9: Postoperative Neurological Status – Intent-to-Treat Cohort

Neurological status[1]	6 Months	
	Surgery + Oxiplex	Surgery Alone
Deteriorated [n (%)]	2 (2.5%)	0 (0.0%)
Not Deteriorated [n (%)]	77 (97.5%)	44 (100.0%)

[1]Neurological status as determined by the Clinical Events Committee.

The overall adverse event rate for the Surgery + Oxiplex group (49.4%) was not clinically or statistically different from the adverse event rate for the Surgery alone control group (51.1%; p=0.999, Exact). Although the incidence of device- or procedure-related adverse events was higher in the Surgery + Oxiplex group (14.9%) compared to the Surgery Alone control group (8.5%), this difference was not statistically significant (p=0.416, Exact). The study demonstrated a very low rate of device-related adverse events with zero (0) events (in 0.0% of Surgery + Oxiplex subjects) considered by the clinical events committee (CEC) to be definitely-related to the device and only two (2) events (in 2.3% of Surgery + Oxiplex subjects) considered by the CEC to be possibly-related to the device (severe hematoma and mild lumbar radiculopathy, both experienced on the day of procedure). No subject deaths or unanticipated adverse events occurred.

CONCLUSIONS FROM CLINICAL DATA

The clinical data support several adjunctive benefits from the use of Oxiplex with spinal surgery, including a more complete reduction in ipsilateral leg pain and reduced neurological symptoms. There is an increased likelihood of achieving high or complete resolution of ipsilateral leg pain at 6 Months (9% more Oxiplex subjects achieved at least 80% reduction, 11% more Oxiplex subjects achieved at least 90% reduction, 5% more Oxiplex subjects achieved 100% reduction).

Clinically meaningful improvements for Oxiplex subjects are demonstrated in total SBI score at 6 Months (4% more Oxiplex subjects achieved a minimum 9.0 point improvement in total SBI score, 23.4% more Oxiplex subjects achieved at least 80% reduction, 24.3% more Oxiplex

subjects achieved at least 90% reduction, 11% more Oxiplex subjects achieved 100% reduction).

The clinical data also support a very low incidence of Oxiplex device-related adverse events with no adverse events being definitely related to the device, and no significant differences in adverse event categories between groups. Overall, there was a similar rate of surgical interventions for both groups, a lower rate of secondary surgical interventions due to reherniation for Oxiplex subjects, and low rates of deterioration in neurological status for both groups.

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Comments regarding the performance of this device in the USA can be directed to manufacturer above.

ORDERING INFORMATION

REF	Item Description	Item Number
	Oxiplex Absorbable Gel, 3mL	FPC-09010
	Oxiplex Absorbable Gel, 1.5mL	FPC-09020

SYMBOL GLOSSARY

Symbol	Ref	Title	Symbol	Ref	Title
	5.1.1*	Manufacturer	Rx Only	21 CFR 801.109(b)(1)	For prescription use only
	5.1.4*	Use-by-date		5.3.7*	Temperature limit
LOT	5.1.5*	Batch code	STERILE	5.2.5*	Sterilized using steam or dry heat
REF	5.1.6*	Catalogue number		5.4.2*	Do not re-use
	5.2.11*	Single sterile barrier system		5.4.3*	Consult instructions for use
MD	5.7.7*	Medical device	MR	6.4.4.1**	MR safe

**ISO 15223-1* ***ASTM F2503*

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Oxiplex® Absorbable Gel for Spine Surgery Reimbursement Guide

This Reimbursement Guide has been developed specifically for healthcare providers and professionals responsible for coding and reporting provided services. It does not constitute legal, reimbursement, business, clinical, or other advice. Healthcare providers are solely responsible for determining appropriate charging and billing practices, as well as accurate coding, documentation, and medical necessity for the services provided. This includes the responsibility for the accuracy and veracity of all claims submitted to third-party payers.

Introduction

The purpose of this guide is to provide coverage, coding, and payment information relating to Oxiplex Absorbable Gel for Spine Surgery. Oxiplex is a synthetic, absorbable gel intended as an adjunct to lumbar spinal surgery in adult patients with leg pain, back pain, and neurological symptoms undergoing discectomy to reduce leg pain and neurological symptoms. While this guide includes CPT codes for various spine procedures, it is important to note that the selection of the most appropriate procedure code is the responsibility of the coder, who should follow the specific guidance provided by the payer. This guide includes procedure codes that may be used in conjunction with or alongside Oxiplex. These additional codes are provided for reference purposes only and do not imply endorsement or recommendation for use with any other products.

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Hospital Inpatient Coding and Payment

Potential Procedures Using Oxiplex Absorbable Gel – Inpatient Setting

ICD-10-PCS Code[1]	Code Descriptor
Release / Lumbar Spinal Cord	
00NY0ZZ	Release Lumbar Spinal Cord, Open Approach
00NY3ZZ	Release Lumbar Spinal Cord, Percutaneous Approach
00NY4ZZ	Release Lumbar Spinal Cord, Percutaneous Endoscopic Approach
Replacement / Lumbar Vertebral Disc	
0SR20JZ	Replacement of Lumbar Vertebral Disc with Synthetic Substitute, Open Approach
Excision / Lumbar Vertebral Disc	
0SB20ZZ	Excision of Lumbar Vertebral Disc, Open Approach
0SB23ZZ	Excision of Lumbar Vertebral Disc, Percutaneous Approach
0SB24ZZ	Excision of Lumbar Vertebral Disc, Percutaneous Endoscopic Approach
Excision / Lumbar Vertebral Joint	
0SB00ZZ	Excision of Lumbar Vertebral Joint, Open Approach
0SB00ZX	Excision of Lumbar Vertebral Joint, Open Approach, Diagnostic
0SB03ZZ	Excision of Lumbar Vertebral Joint, Percutaneous Approach
0SB03ZX	Excision of Lumbar Vertebral Joint, Percutaneous Approach, Diagnostic
0SB04ZZ	Excision of Lumbar Vertebral Joint, Percutaneous Endoscopic Approach
0SB04ZX	Excision of Lumbar Vertebral Joint, Percutaneous Endoscopic Approach, Diagnostic
Resection / Lumbar Vertebral Disc	
0ST20ZZ	Resection of Lumbar Vertebral Disc, Open Approach

ICD-10-PCS Coding Table for Lumbar Spinal Fusions		
Section	**0**	**Medical and Surgical**
Body System	**S**	**Lower Joints**
Operation	**G**	**Fusion**

Body Part	Approach	Device	Qualifier
0 Lumbar Vertebral Joint 1 Lumbar Vertebral Joints, 2 or more 3 Lumbosacral Joint	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	7 Autologous Tissue Substitute J Synthetic Substitute K Nonautologous Tissue Substitute	0 Anterior Approach, Anterior Column 1 Posterior Approach, Posterior Column J Posterior Approach, Anterior Column
0 Lumbar Vertebral Joint 1 Lumbar Vertebral Joints, 2 or more 3 Lumbosacral Joint	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	A Interbody Fusion Device	0 Anterior Approach, Anterior Column J Posterior Approach, Anterior Column

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Potential MS-DRGs Using Oxiplex Absorbable Gel – Inpatient Setting

MS-DRG	MS-DRG Title	2026 Medicare MS-DRG Payment[2]
28	Spinal Procedures with MCC	$43,720.96
29	Spinal procedures with CC or spinal neurostimulators	$24,825.39
30	Spinal procedures without CC/MCC	$15,973.94
402	Single level combined anterior and posterior spinal fusion except cervical	$29,256.21
426	Multiple level combined anterior and posterior spinal fusion except cervical with MCC or custom-made anatomically designed interbody fusion device	$80,198.63
427	Multiple level combined anterior and posterior spinal fusion except cervical with CC	$52,528.02
428	Multiple level combined anterior and posterior spinal fusion except cervical without CC/MCC	$40,909.94
447	Multiple level spinal fusion except cervical with MCC or custom-made anatomically designed interbody fusion device	$48,620.40
448	Multiple level spinal fusion except cervical without MCC	$30,859.28
450	Single level spinal fusion except cervical with MCC or custom-made anatomically designed interbody fusion device	$38,782.22
451	Single level spinal fusion except cervical without MCC	$23,506.85
456	Spinal fusion except cervical with spinal curvature, malignancy, infection, or extensive fusions with MCC	$61,149.52
457	Spinal fusion except cervical with spinal curvature malignancy, infection, or extensive fusions with CC	$43,392.05
458	Spinal fusion except cervical with spinal curvature, malignancy, infection, or extensive fusions without CC/MCC	$30,363.01
518	Back and neck procedures except spinal fusion with MCC or disc device or neurostimulator	$27,195.44
519	Back or neck procedures except spinal fusion with CC	$14,554.98
520	Back or neck procedures except spinal fusion without CC/MCC	$10,870.75
820	Lymphoma and leukemia with major O.R. procedures with MCC	$42,676.74
821	Lymphoma and leukemia with major O.R. procedures with CC	$16,289.75
822	Lymphoma and leukemia with major O.R. procedures without CC/MCC	$8,761.22

MS-DRG	MS-DRG Title	2026 Medicare MS-DRG Payment[2]
826	Myeloproliferative disorders or poorly differentiated neoplasms with major O.R. procedures with MCC	$34,039.23
827	Myeloproliferative disorders or poorly differentiated neoplasms with major O.R. procedures with CC	$16,818.05
828	Myeloproliferative disorders or poorly differentiated neoplasms with major O.R. procedures without CC/MCC	$12,398.14
907	Other O.R. procedures for injuries with MCC	$27,937.66
908	Other O.R. procedures for injuries with CC	$14,518.59
909	Other O.R. procedures for injuries without CC/MCC	$9,552.20
957	Other O.R. procedures for multiple significant trauma with MCC	$55,448.18
958	Other O.R. procedures for multiple significant trauma with CC	$30,663.54
959	Other O.R. procedures for multiple significant trauma without CC/MCC	$21,423.51

Commonly used **revenue codes**, depending on your facility, may include:

- **0272** Medical/Surgical Supplies and Devices: Sterile
- **0278** Medical/Surgical Supplies and Devices: Other implants
- **0279** Medical/Surgical Supplies and Devices: Other supplies/devices

If the facility's policy is to track absorbable gel use, assign a code from **Table 3E0** (refer to linked file at: https://www.cms.gov/files/zip/2026-icd-10-pcs-code-tables-and-index.zip) that best matches the **documented site** (spinal canal vs. soft tissue/fascia) and **approach** (open, percutaneous, percutaneous endoscopic). Only code what the operative notes explicitly support.

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Hospital Outpatient Coding and Payment

Potential Procedures Using Oxiplex Absorbable Gel – Hospital Outpatient Setting

HCPCS/CPT Code[3]	Descriptor	APC	APC Amount[4]
Spinal Osteotomy: Anterior Approach			
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	5114	$7,413.38
+22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
Spinal Fusion: Lateral Extracavitary Approach			
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	5116	$17,913.59
+22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
Spinal Fusion: Anterior and Posterior Approach			
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	5117	$27,721.73
+22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace	5116	$17,913.59
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)	5116	$17,913.59
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar	5117	$27,721.73

HCPCS/CPT Code[3]	Descriptor	APC	APC Amount[4]
Spinal Fusion: Anterior and Posterior Approach			
+22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar	5117	$27,721.73
+22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
Artificial Disc Replacement			
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	5116	$17,913.59
+22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	Inpatient Only	
Posterior Midline Approach: Laminectomy/Laminotomy/Decompression			
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	5114	$7,413.38
+63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar	5114	$7,413.38

HCPCS/CPT Code[3]	Descriptor	APC	APC Amount[4]
Posterior Midline Approach: Laminectomy/Laminotomy/Decompression			
+63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
Spinal Cord/Nerve Root Decompression: Costovertebral or Transpedicular Approach			
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar	5114	$7,413.38
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)	5114	$7,413.38
+63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)	Packaged into the primary APC payment	
Other: Category II, Category III, Unlisted, or New Technology Procedure C-Codes			
C1889	Implantable/insertable device, not otherwise classified	Packaged into the primary APC payment	
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment	Not paid by Medicare when submitted on outpatient claims	
22899	Unlisted procedure, spine	5111	$252.01
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar	5115	$13,116.76

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Ambulatory Surgical Center (ASC) Coding and Payment

Potential Procedures Using Oxiplex Absorbable Gel – Ambulatory Surgery Center Setting

CPT Code[3]	Descriptor	ASC Amount[4]
Spinal Osteotomy: Anterior Approach		
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	$3,695.53
+22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)	Excluded from payment in ASCs
Spinal Fusion: Lateral Extracavitary Approach		
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	$9,255.83
+22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)	Excluded from payment in ASCs
Spinal Fusion: Anterior and Posterior Approach		
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	$20,101.23
+22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)	Packaged
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace	$11,727.25
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)	$13,491.52
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar	$20,858.55
+22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	Packaged

CPT Code[3]	Descriptor	ASC Amount[4]
Spinal Fusion: Anterior and Posterior Approach		
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar	$20,841.42
+22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	N/A
Artificial Disc Replacement		
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	$12,699.87
+22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	Packaged
Posterior Midline Approach: Laminectomy/Laminotomy/Decompression		
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	$3,695.53
+63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)	Packaged
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar	$3,695.53
+63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)	Packaged

CPT Code[3]	Descriptor	ASC Amount[4]
Spinal Cord/Nerve Root Decompression: Costovertebral or Transpedicular Approach		
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)	$3,695.53
+63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)	Packaged
Other: Category III, Unlisted, or Special Conditions		
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment	N/A
22899	Unlisted procedure, spine	Excluded from payment in ASCs
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar	$3,695.53
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar	$9,696.16

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Physician Coding and Payment

Beginning January 1, 2026, Medicare will determine payment based on two separate conversion factors, depending on whether the physician participates in an Advanced Alternative Payment Model (APM).

Payment rates for both qualifying and non-qualifying physicians are included in the following section.

Potential Procedures Using Oxiplex Absorbable Gel – Physician Fee Schedule - Facility

CPT code[3]	Descriptor	Work RVUs	Facility Total RVUs	2026 Payment Rate[5] (Qualifying Physician)	2026 Payment Rate[5] (Non-Qualifying Physician)
Spinal Osteotomy: Anterior Approach					
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	22.51	44.33	$1,488.05	$1,480.66
+22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)	5.88	9.57	$321.24	$319.65
Spinal Fusion: Lateral Extracavitary Approach					
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	24.17	46.34	$1,555.52	$1,547.80
+22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)	5.84	9.68	$324.93	$323.32
Spinal Fusion: Anterior and Posterior Approach					
22558	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	22.94	42.64	$1,431.32	$1,424.21

CPT code[3]	Descriptor	Work RVUs	Facility Total RVUs	2026 Payment Rate[5] (Qualifying Physician)	2026 Payment Rate[5] (Non-Qualifying Physician)
Spinal Fusion: Anterior and Posterior Approach					
+22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)	5.38	8.61	$289.02	$287.58
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace	27.42	60.11	$2,017.74	$2,007.73
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)	22.94	43.93	$1,474.62	$1,467.30
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (List separately in addition to code for primary procedure)	6.27	10.46	$351.12	$349.37
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar	21.54	45.22	$1,517.92	$1,510.39
+22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	5.09	8.61	$289.02	$287.58

CPT code[3]	Descriptor	Work RVUs	Facility Total RVUs	2026 Payment Rate[5] (Qualifying Physician)	2026 Payment Rate[5] (Non-Qualifying Physician)
Spinal Fusion: Anterior and Posterior Approach					
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar	26.13	50.88	$1,707.91	$1,699.44
+22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	7.76	12.94	$434.36	$432.21
Artificial Disc Replacement					
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	26.45	46.98	$1,577.00	$1,569.17
+22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	6.71	10.31	$346.08	$344.36
Posterior Midline Approach: Laminectomy/Laminotomy/Decompression					
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	11.70	26.89	$902.63	$898.15

CPT code[3]	Descriptor	Work RVUs	Facility Total RVUs	2026 Payment Rate[5] (Qualifying Physician)	2026 Payment Rate[5] (Non-Qualifying Physician)
Posterior Midline Approach: Laminectomy/Laminotomy/Decompression					
+63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)	3.76	6.18	$207.45	$206.42
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar	18.29	36.53	$1,226.22	$1,220.13
+63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)	Contractor Priced			
Spinal Cord/Nerve Root Decompression: Costovertebral or Transpedicular Approach					
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)	21.31	42.04	$1,411.18	$1,404.17
+63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)	5.12	8.61	$289.02	$287.58

CPT code[3]	Descriptor	Work RVUs	Facility Total RVUs	2026 Payment Rate[5] (Qualifying Physician)	2026 Payment Rate[5] (Non-Qualifying Physician)
Other: Category III, Unlisted, or Special Conditions					
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment		Contractor Priced		
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar		Contractor Priced		
22899	Unlisted procedure, spine		Contractor Priced		

References

1. ICD-10-PCS 2026: The Complete Official Codebook. American Medical Association; 2025.
2. 2026 CMS IPPS Final Rule, Tables 1B, 1D, and 5 (available on CMS' website), 90 Fed. Reg. 147 (August 4, 2025).
3. CPT Copyright 2025 American Medical Association. All rights reserved. AMA and CPT are registered trademarks of the American Medical Association.
4. 2026 CMS OPPS/ASC Final Rule, Addendum B and AA (available on CMS website), CMS-1834-FC (Nov. 25, 2025).
5. 2026 CMS PFS Final Rule, CMS-1832-F, Addendum B (available on CMS website, Correction notice dated November 3, 2025). Non-Qualifying Physician Conversion factor on January 1, 2026: $33.4009. Qualifying Physician Conversion factor on January 1, 2026: $33.5675.

Fziomed Reimbursement Support

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Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See *Specific Instructions* on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Fziomed, Inc.

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☑ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☐ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) . . . . .

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions . . . . . ☐

5 Address (number, street, and apt. or suite no.). See instructions.

231 Bonetti Drive

Requester's name and address (optional)

6 City, state, and ZIP code

San Luis Obispo, CA 93401

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

7	7	–	0	4	4	2	6	0	6

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** | **Date** 5/20/26

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they